



PLASTIC SURGERY
EDUCATIONAL FOUNDATION



THE AMERICAN SOCIETY FOR
AESTHETIC PLASTIC SURGERY, INC.

The Silicone Breast Implant *Education Symposium*

Breast Implant Registry, FDA Requirements, And Worldwide Efforts

ASPS/PSEF – ASAPS

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DRAFT

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Outline Of Topics Covered

- National Breast Implant Registry
- FDA silicone gel implant requirements
- Value of registries
- Data entry
- Data tabulations on implants and patients
- International Breast Implant registry
 - status of registries around the world

History of NaBIR

- National Breast Implant Registry (NaBIR) started July 2001 by PSEF
- Participation is voluntary
- Now > 100 centers participating
- PSEF goal is to make registry inclusive
 - get every surgeon to participate
 - capture data on every implant

Greater Participation Needed

- All surgeons who perform augmentation should be involved
 - Not just a small percentage
- FDA has mandated a national registry as a condition of future PMA approval for silicone gel implants
 - One of suggestions arising from Oct. 2003 advisory panel meeting

FDA Conditions For Approval

- *Mentor will participate in maintaining a patient registry that is independently managed by a professional organization that will track patients who use the product during their lifetime*

Registry Status

- PSEF is negotiating with FDA and the manufacturers to make NaBIR the official registry for all breast implants

Possible Funding

- Largest expense is database maintenance
 - PSEF cannot afford to maintain a larger registry alone
- Manufacturers have not been paying
- Funding mechanism is needed to sustain and expand the registry
 - One idea: a \$10 tariff for each implant sold that is managed by PSEF
 - Excess money could be used for research

Why Have A Registry?

- Provide data on pattern of device use
- Help to identify implant problems
 - track, retrieve, recall
- Provide real-time data independent of manufacturers
 - transparent system gives surgeons access to tabulated data
- Establish a cohort of patients should studies need to be conducted

Why Have A Registry?

- Peer group comparisons and national benchmarks for practice patterns, demographics, outcomes and trends
- Proactive thing to do for patients

Data Entry

- Surgeons / staff enter data online
- Filling out form takes a few minutes
- Surgeon and patient names are confidential
- Database is secure
- Data is updated in real-time as forms are submitted

Data Management

- NaBIR is maintained by Data Harbor, a large data management company
- Mechanisms are in place to prevent tampering with data
- Data tabulations can be viewed at any time by anyone with the database password

Data Collected by Registry

- Patient zip code and date of birth
- Date of procedure
- Implant manufacturer
- Implant type, shape, and filler
- Implant lot and serial number
- Implant volume
 - nominal and actual

Data Collected By Registry

- Indication for surgery
- Implant position
- Incision site

NaBIR Data *Registered by 04/05/04*

- 18,511 implants
- 2,825 explants
- 11,888 surgeries
- Median patient age – 36 years

NaBIR Data

- Median actual fill volume – 375 cc
- Median nominal fill volume – 330 cc
- 76% of implants overfilled from nominal volume
 - median overfill volume = 30 cc
- Median time to explantation = 4 years

Surgery Indications

Cosmetic	77%
Replacement	11%
Reconstruction	10%
Congenital	1%
Other	1%

Implant Type

Smooth	83%
Textured	15%
Expander	1%
Filler Material	
Silicone gel*	6%
Saline	92%
Gel and Saline*	1%

*Data collection began September 2002

Other Implant Variables

Position

Subpectoral	68%
Subglandular	32%

Shape

Round	90%
Contoured	10%

Incision Locations

Axillary	11%
Inframammary	62%
Periareolar	19%
Transumbilical	<1%
Mastectomy scar	7%

Reoperation Indications

Rupture/deflation	33%
Capsular contracture	33%
Change in size	32%
Patient request	17%
Implant migration	8%
Pain*	5%
Abnormal feel*	4%
Wrinkling*	4%
Infection	3%

*Data collection began September 2002

Tumors After Implantation

Benign tumor	<1%
Malignant tumor	1%
Stage I	35%
Stage II	35%
Stage III	30%
Stage IV	0%

*Tumor Identification**

Physical exam	48%
Mammography	45%
Ultrasound	7%
MRI	0%

We can compare the success of
diagnostic methods to those used for
non-augmented women

*Data collection began September 2002

Registry Benefits

- Provides data on large numbers of patients
- Geographically diverse
- Preserves confidentiality

- If registry were redesigned and linked to other data sources, it could help answer difficult questions
 - Incidence of suicide, cancer, reoperation, local complications, and implant failure
- Linkage to outcomes through TOPS



*International Breast Implant
Registry*

**Founding Meeting
IPRAS Annual Meeting
Istanbul, Turkey
May 2002**



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IBIR Participants

- U.S.A.
- Germany
- Mexico
- Israel
- Denmark
- Brazil
- Australia (pending)

Value of IBIR

- Single instrument for data entry makes data gathering and comparison simple
- Computerized data entry and storage speeds up the process
- Each country can gather additional data as desired to meet its needs
- Surgeon and patient confidentiality is ensured

Value of IBIR

- Larger numbers of patients
- Faster accrual of data
- Capture more types of implants
- Identify new, improved techniques
- Spot problems early
- Allow surgeons to demonstrate consistency or variance of results from country to country

Status of Other Registries

- Many countries have established registries
Denmark ❖ UK ❖ US ❖ Austria
- EU parliament mandated breast implant registries for EU countries effective 2004
- Australia and Brazil have registry requirements
- Asia, Africa, and Mideast countries have not addressed the issue